K103070
page 1 of 2

510(k) Summary

(as required by 21 CFR 807.92)

Submitted By: Donald Grafton
G Surgical Co., Ltd.
4218 Skyway Dr
Naples, FL 34112
Ph 239 919 4895
Fax 239 455 8988

JAN 12 2011

Date: Oct. 4, 2010

Sponsor: G Surgical Co., Ltd.
152 Soi Ramkhamhaeng 138
Sapansung, Bangkok
Thailand 10240

Trade Name: GPS ™, Anterior Cervical Plate System
Common Name: Anterior Cervical System
Classification Name: Spinal Intervertebral Body Fixation Orthosis
Device Class: FDA proposed classification as Class II (888.3060) following Orthopedic and Rehabilitation Device Advisory Review, for the requested indications.
Device/Product Code(s): Anterior Cervical Plates (KWQ)
21 CFR § 888.3060

Predicate Devices:

K030866 Synthes CSLP	April 18, 2003
K000536 Synthes CSLP	May 15, 2000
K021461 Medtronic Atlantis Vision®	July 22, 20002

Device Description: The **GPS™** G Surgical Anterior Cervical Plate System consists of a variety of shapes and sizes of bone plates, bone screws, locking screws, and associated instruments. Fixation is provided by bone screws, of various lengths, inserted into the vertebral body of the cervical spine using an anterior approach. The **GPS™** G Surgical Anterior Cervical Plate System implant components are made from titanium alloy described by ASTM F136 and supplied non sterile. Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the GPS ™, G Surgical Pedicle System implants.

Indications for Use: The GPS™, G Surgical Anterior Cervical Plate System is intended for use in anterior cervical decompression and fusion (ACDF) surgery at levels C2-C7. The system is indicated for temporary stabilization of the anterior spine during the development of cervical fusions in skeletally mature patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of the discogenic origin with degeneration of disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors

- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Spondylolisthesis
- Spinal Stenosis

Warning: The device is not intended for screw attachments or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Performance Data: Performance testing was performed on the **GPS™** G Surgical Anterior Cervical Plate System included static compression, dynamic compression and static torsion in accordance with ASTM F1717. The test results demonstrate the **GPS™** G Surgical Anterior Cervical Plate System is safe and effective and adequate for the intended use. No clinical testing was performed.

Substantial Equivalence: The **GPS™** G Surgical Anterior Cervical Plate System is equivalent to the predicate devices in design, function and indications of use. The results of non clinical testing demonstrate that the mechanical performance of the **GPS™** G Surgical Anterior Cervical Plate System is equivalent to the predicate devices. Thus the **GPS™** G Surgical Anterior Cervical Plate System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

G Surgical Co., Ltd.
% Mr. Donald Grafton
152 Soi Ramkhamhaeng 138
Sapansung, Bangkok
Thailand 10240

JAN 12 2011

Re: K103070
Trade/Device Name: GPS™, G Surgical Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: December 16, 2010
Received: December 17, 2010

Dear Mr. Grafton:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103070
page 1 of 1

INDICATIONS FOR USE

JAN 12 2011

Device Name GPS™, G Surgical Anterior Cervical Plate System

Indications for Use: The GPS™, G Surgical Anterior Cervical Plate System is intended for use in anterior cervical decompression and fusion (ACDF) surgery at levels C2-C7. The system is indicated for temporary stabilization of the anterior spine during the development of cervical fusions in skeletally mature patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of the discogenic origin with degeneration of disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Spondylolisthesis
- Spinal Stenosis

Warning: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Prescription Use __X___ AND/OR Over the Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103070